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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,214	07/09/2001	Gordon L. Amidon	PSL-10202/39	6240

7590 08/13/2003
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EXAMINER

HUI, SAN MING R

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 08/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/901,214

Applicant(s)

AMIDON ET AL.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Applicant's amendments filed May 15, 2003 have been entered.

The cancellation of claims 12-20 is acknowledged.

The outstanding rejection under 35 USC 112, first paragraph is withdrawn in view of the amendments filed May 15, 2003.

The outstanding rejections of claims 1 and 12 with regard to the expression "maintaining a region adjacent to said drug particle" and "contains solubilizing agent micelles to solubilize same through..." under 35 USC 112, second paragraph are withdrawn in view of the amendments and remarks filed May 15, 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "drug disposed in the drug particle has a solubility greater than twofold that of said drug in a bulk form..." in claims 1 and 12 renders the claims indefinite because it is unclear to one of ordinary skill in the art if the drug disposed in the drug particle and that in a bulk form are having the same particle size or not. Without expressly stating such properties, one of ordinary skill in the art would not be able to ascertain the proper materials to practice the instant invention. In other words, it is unclear how such increase in dissolution rate would be able to be accomplished.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amidon et al. (US Patent 5,834,022) in view of Woo (US Patent 5,589,455) and Gennaro et al. (Remington's Pharmaceutical Sciences, 18th ed., 1990, page 1662-1664), references of record.

Amidon et al. teaches a coating (the boundary layer) composition consisting essentially of gelatin (a matrix) and lecithin (solubilizing agent) and in which the drug are disposed within the boundary layer (See particularly col. 9, line 15 – col. 12, line 19). Amidon et al. also teaches cyclosporin and griseofluvin (the drug actives) have dissolution rates of both drugs increased to about 20% and 40% respectively when employed the lecithin/gelatin coating drug delivery system (See particularly col. 6, lines 3-13; also Figures 2-7).

Amidon et al. does not expressly teach that the coating composition contains emulsion or microemulsion or micelles. Amidon et al. does not expressly teach that the matrix that formed the boundary layer comprises a film.

Woo teaches that a microemulsion may be used in a soft capsule pharmaceutical formulation to enhance the solubility of a poorly soluble drug, cyclosporin (See particularly abstract, also 4, line 53 to col. 7, line 13).

Gennaro et al. teaches that a gelatin film may be used in the preparation of soft gelatin capsules (See particularly page 1663, col. 2, second paragraph).

It would have been obvious to one skill in the art when the invention was made to incorporate microemulsion and the film into the composition of Amidon et al.

One of ordinary skill in the art would have motivated to incorporate microemulsion and the film into the composition of Amidon et al. because both microemulsion and the film are well known in the art to be useful in poorly-soluble enhancement formulation, based on Woo and Gennaro et al. Therefore, absent evidence to the contrary, combining agents which are known to be useful to enhance drug solubility individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069. Please note that the formation of micelles is depending on the concentration of the surfactant, so called critical micelle concentration. Since the cited prior art teaches the herein claimed surfactant, adjusting the concentration of the surfactants, either to form emulsions or micelles, are within the purview of the skilled artisan.

Response to Arguments

Applicant's arguments filed May 15, 2003 averring the cited prior art's failure to teach the quantity of drug relative to the boundary layer have been considered but are not found persuasive. Examiner notes that the instant claims are drawn to a

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composition. The instant claims merely recite functional language in attempt to define the relationship between the amount of the drug and the thickness of the boundary layer. Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claims is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". Claims employing functional language at the point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limits of the monopoly asserted" *General Electric Company v. Wabash Appliance Corporation et supra*, at 468. Claims thus constructed provide no guidance as to medicaments employed, levels for providing therapeutic benefit, or provide notice for those practicing in the art, limits of protection. Simply stated, the presented claims are an invitation to experiment, not reciting specific dimensions of the drug particles relative to the boundary layer useful for practicing the instant invention. Moreover, the cited prior art teaches every component recited in the claims. Absent showing the criticality of a specific ratio between the drug particles and the thickness of the boundary layer

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(which did not recited in the claims), one of ordinary skill in the art would have been motivated to optimize the particle size of the drug in order to increase or decrease the dissolution rate the of the drug.

Applicant's rebuttal arguments filed May 15, 2003 averring the cited prior art's failure to teach the boundary layer control parameters have been considered, but are not found persuasive. It is not clear what specific boundary layer control parameters the applicant refers to. The instant claims are not seen to recite such parameters.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-

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1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
August 11, 2003



RUSSELL TRAVERS
PRIMARY EXAMINER